

Original Studies

Retrograde Popliteal Access as Bail-Out Strategy for Challenging Occlusions of the Superficial Femoral Artery: A Multicenter Registry

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Background: The concomitant use of femoral and popliteal accesses has been recommended for challenging superficial femoral artery (SFA) occlusions, but no comprehensive comparison of this approach to a strategy of femoral access only is available. We thus aimed to appraise the risk-benefit balance of retrograde popliteal access as bail-out strategy for SFA occlusions. **Methods:** Consecutive patients with symptomatic SFA occlusion and undergoing percutaneous revascularization were enrolled. We distinguished patients in whom retrograde popliteal access was required as bail-out strategy versus those not requiring such access. The primary end-point was procedural success. **Results:** A total of 130 patients (152 limbs) were included, with 23 patients (25 limbs) requiring retrograde popliteal access. Occlusion length was 20.6 ± 8.8 cm in those requiring popliteal access versus 18.5 ± 8.5 cm in those without popliteal access, with TASC C/D lesions in 23 (92%) versus 106 (83%). Procedural success was achieved in 92 out of 107 patients (86.0%) treated with a standard approach and 22 out of 23 patients (95.7%) treated with retrograde popliteal access (total 114 out of 130 [87.7%]) and 112 out of 127 limbs (88.2%) and 24 out of 25 limbs (96.0%), respectively (total 136 out of 152 [89.5%]). No significant increase in early or long-term adverse events was associated with retrograde popliteal access. **Conclusions:** Whenever standard access sites do not enable successful recanalization of SFA occlusions, retrograde popliteal access can be safely and effectively envisioned as bail-out strategy. © 2012 Wiley Periodicals, Inc.

Key words: angioplasty; femoral; peripheral artery disease; popliteal

INTRODUCTION

The burden of peripheral artery disease is increasing due to worldwide increases in life expectancy, obesity, and diabetes [1]. Symptomatic lower limb atherosclerosis

most commonly involves the superficial femoral artery (SFA), with complex lesions and occlusions commonly and diffusely involving this thigh vessel. Although surgical bypass grafting is still considered the best

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management strategy for symptomatic atherosclerotic SFA disease, it remains associated with morbidity [1,2].

Endovascular therapy has seen major improvements in the last decades with the introduction of several dedicated techniques (e.g., subintimal angioplasty) [3] and devices (e.g., re-entry devices and stents) [3,4]. This has led to favorable clinical outcomes that closely match those of surgical therapy, especially in patients with critical limb ischemia [2]. However, success rates of endovascular treatment for SFA occlusions remain suboptimal, especially due to problems in re-entry after extensive subintimal tracking of guidewires [2–4].

Retrograde popliteal access has been proposed as a safe and effective means to increase success rate of percutaneous transluminal angioplasty (PTA) for SFA occlusions, after failed antegrade attempt by means of ipsilateral or contralateral femoral (or occasionally brachial or axillary) access [5,6]. The rationale for this increased success rate is that the distal occlusion stump in this vessel as well as in others is usually tapered, thereby increasing the likelihood of intraluminal seating of guidewires [7–9]. However, only few studies have been reported, without systematic comparison to a standard (i.e., femoral or brachial) approach [5,6,10–18].

Hypothesizing that retrograde popliteal approach is safe and effective when employed as a bail-out strategy, we appraised the risk-benefit balance of bail-out retrograde popliteal access as strategy for SFA occlusions in the setting of a multicenter retrospective study.

METHODS

Study Design and Patient Population

This study was based on a dedicated electronic data capturing system. Given the observational design, institutional review board approval was waived.

Consecutive patients with symptomatic lower limb ischemia and angiographic evidence of total occlusion of the SFA were included in case endovascular treatment of the SFA occlusion was attempted. All patients provided written informed consent.

Procedures

Percutaneous transluminal angioplasty was first attempted by means of ipsilateral or contralateral femoral access, or occasionally by means of brachial approach, with the decision for this “default” access at the operator’s discretion. Standard and subintimal angioplasty techniques were employed for SFA recanalization, using 0.035”, 0.018”, and 0.014” guidewires, both nonhydrophilic and hydrophilic, supported by hydrophilic catheters or compatible balloons. If intralu-

menal or subintimal angioplasty was successful, stenting was performed with self-expandable stents in case of significant residual stenosis or flow-limiting dissection after balloon-only intervention.

In case of failure of femoral access only PTA, retrograde popliteal access was attempted at the operator’s discretion. In general, all cases in which the popliteal artery was free of significant disease for at least 40 mm were considered suitable for retrograde popliteal access. Conversely, diffuse significant atherosclerotic involvement or dissection of the popliteal artery were considered contraindications to popliteal access. Retrograde popliteal access was attempted in all cases during the index procedure, to exploit the combined femoral and popliteal accesses according to the controlled antegrade and retrograde subintimal tracking technique (CART)/subintimal arterial flossing with antegrade-retrograde intervention (SAFARI) [15,19].

In case popliteal access was attempted, the patient was turned in a prone position, and the popliteal artery was punctured under angiographic guidance with a 18G needle, enabling the deployment of a 4Fr 11 cm sheath (Cordis, Miami, FL). Through the sheath, 0.035”, 0.018”, and 0.014” guidewires, both nonhydrophilic and hydrophilic, were advanced retrogradely supported by hydrophilic catheters or compatible balloons. In case of subintimal tracking, care was taken to ensure true lumen re-entry not more proximally than the SFA ostium to avoid jeopardizing the profunda femoris artery. If intraluminal or subintimal angioplasty was successful by the retrograde route, a wire was deployed either antegradely from the femoral access or retrogradely from the popliteal access and the procedure completed with additional balloon dilations and self-expandable stenting in case of significant residual stenosis or flow-limiting dissection after balloon-only intervention. In case of inability to cross the occlusion or to intraluminal re-entry by both femoral and popliteal route, no further attempt was conducted and the procedure was interrupted. Hemostasis at the femoral access was achieved by either manual compression or closure devices, whereas hemostasis at the popliteal or brachial accesses was managed with manual compression only in all cases, with compression typically lasting 3 minutes for each sheath French [20].

All patients were pretreated or loaded peri-procedurally with aspirin and clopidogrel, with discharge dual antiplatelet therapy for 1 month in all patients undergoing PTA. Peri-procedural anticoagulation was based on weight-adjusted (70 IU/Kg) unfractionated heparin aiming to achieve an activated clotting time >250 s. After discharge, patients were followed clinically and by means of duplex ultrasound, with repeat angiography in case of symptoms or imaging evidence of restenosis.

TABLE I. Baseline Characteristics

	Standard access (patients = 107; limbs = 127)	Retrograde popliteal access (patients = 23; limbs = 25)	<i>P</i> value
Male gender	76 (71%)	19 (83%)	0.256
Age (years)	71 ± 10	71 ± 10	0.955
Prior myocardial infarction	32 (30%)	9 (39%)	0.404
Prior coronary artery bypass grafting	24 (22%)	3 (13%)	0.405
Prior percutaneous transluminal angioplasty	27 (26%)	5 (22%)	0.707
Prior lower limb bypass grafting	13 (12%)	0	0.123
Hypertension	49 (46%)	19 (83%)	0.001
Dyslipidemia	32 (30%)	10 (44%)	0.207
Cigarette smoking			0.076
Former	29 (27%)	3 (13%)	
Current	11 (10%)	6 (26%)	
Family history of cardiovascular disease	14 (13%)	3 (13%)	1.0
Chronic renal failure	15 (14%)	1 (4%)	0.302
Diabetes mellitus			0.120
Noninsulin dependent	22 (21%)	9 (39%)	
Insulin dependent	53 (50%)	7 (30%)	
Baseline Fontaine class			0.500
I	18 (14%)	4 (16%)	
II	44 (35%)	7 (28%)	
III	3 (2%)	2 (8%)	
IV	63 (50%)	12 (48%)	

Definitions and End-points

The primary end-point of the study was the rate of procedural success, defined as angiographic success (<20% diameter stenosis without flow-limiting dissection) in the absence of in-hospital death, bypass surgery, acute limb ischemia requiring thrombolysis or other interventions, and thrombolysis in myocardial infarction major bleeding of a femoral only access versus a femoral plus popliteal access. Other end-points included the occurrence of significant (>5 cm) groin hematoma, rehospitalization, amputation, and primary patency, defined as lack of significant (>50%) restenosis or occlusion at follow-up imaging (e.g., duplex ultrasound), with repeat angiography being performed only in patients with recurrent symptoms or requiring staged procedures.

Statistical Analysis

Categorical variables are reported as *n* (%) and were compared with the chi-squared or Fisher exact tests. Continuous variables are reported as mean ± standard deviation and were compared with Student *t* test. A two-tailed *P* value of 0.05 was considered statistically significant. All calculations were performed with SPSS 18 (IBM, Armonk, NY).

TABLE II. Lesion and Procedural Data

	Standard access (patients = 107; limbs = 127)	Retrograde popliteal access (patients = 23; limbs = 25)	<i>P</i> value
Prior percutaneous transluminal angioplasty on target vessel	27 (21%)	1 (4%)	0.048
Prior stenting on target vessel	12 (9%)	2 (8%)	1.0
Occlusion length (cm)	18.5 ± 8.5	20.6 ± 8.8	0.498
Severe calcification	11 (18%)	4 (25%)	0.495
TASC type C/D	106 (83%)	23 (92%)	0.371
Default access site			0.901
Antegrade ipsilateral femoral	16 (13%)	3 (12%)	
Retrograde contralateral femoral	110 (86%)	22 (88%)	
Brachial access	1 (1%)	0	
Default access sheath size (Fr)			0.070
4	59 (47%)	6 (24%)	
6 or more	68 (53%)	19 (76%)	
Default access sheath length (cm)			<0.001
11	85 (67%)	6 (24%)	
15	1 (1%)	0	
45 or more	40 (32%)	19 (76%)	
Popliteal access sheath size (Fr)			–
4	–	25 (100%)	
6 or more	–	0	
Popliteal access sheath length (cm)			–
11	–	25 (100%)	
Good distal run-off	46 (73%)	8 (53%)	0.211
Balloon diameter (mm)	5.5 ± 0.9	5.8 ± 0.7	0.130
Balloon pressure (ATM)	12.4 ± 3.4	11.6 ± 2.3	0.349
Balloon length (mm)	109 ± 53	102 ± 44	0.539
Stent implantation	46 (40%)	13 (59%)	0.098
Stent diameter (mm)	6.4 ± 0.9	6.4 ± 0.5	0.936
Total stent length (mm)	158 ± 75	143 ± 76	0.540
Post-procedural diameter stenosis (%)	17 ± 34	8 ± 21	0.091

RESULTS

Baseline and Lesion Characteristics

A total of 130 patients were included, treated on 152 limbs (Table I). Of these, 107 (82%) patients (127 [84%] limbs) were treated with standard access sites without attempting retrograde popliteal access, in comparison to 23 (18%) patients (25 [16%] limbs), which required retrograde popliteal access. Specifically, femoral access, either antegrade or retrograde, was performed in all cases but one. This patient was treated by means of brachial access, as he had previously been treated with kissing stenting in both common iliac arteries and both antegrade ipsilateral and retrograde contralateral femoral access were unfeasible. Diabetes

TABLE III. Outcome Data

	Standard access (patients = 107; limbs = 127)	Retrograde popliteal access (patients = 23; limbs = 25)	<i>P</i> value
In-hospital death	0	0	1.0
In-hospital major bleeding	2 (2%)	0	1.0
In-hospital groin hematoma	3 (3%)	0	1.0
Clinical follow-up duration (months)	13 ± 12	15 ± 14	0.481
Death during follow-up	4 (4%)	1 (5%)	1.0
Rehospitalization during follow-up	12 (25%)	2 (15%)	0.713
Bypass grafting during follow-up	2 (2%)	1 (5%)	0.462
Amputation during follow-up	1 (1%)	0	1.0
Fontaine class at follow-up			0.519
I	40 (34%)	8 (36%)	
II	7 (6%)	3 (14%)	
III	5 (4%)	2 (9%)	
IV	65 (56%)	9 (41%)	
Primary patency	101 (80%)	21 (86%)	0.786

mellitus was highly prevalent in both groups, respectively, in 75 (71%) versus 16 (69%), and critical limb ischemia was reported as admission diagnosis in 66 (52%) versus 14 (56%).

Most occlusions were long and complex (Table II), with lesion length of 18.5 ± 8.5 cm versus 20.6 ± 8.8 cm ($P = 0.498$), with TASC type C or D lesions in 106 (83%) versus 23 (92%, $P = 0.371$). Prior percutaneous target vessel intervention was more common in the standard access group (39 [30%] versus 3 [12%], $P = 0.056$), with the difference mainly due to prior balloon angioplasty (27 [21%] versus 1 [4%], $P = 0.048$) in comparison to stenting (12 [9%] versus 2 [8%], $P = 1.0$). Such differences may have impacted on failure and recurrence rates, as restenoses are typically at higher risk of failure and recurrence [21].

Procedural and Outcome Data

Standard access sites were employed to recanalize the SFA occlusions by either intraluminal or subintimal approach in most patients, with guidewires of increasing aggressiveness, stiffness, and hydrophilicity. Short and small diameter sheaths were used in case of antegrade femoral approach, whereas longer and larger sheaths were employed for contralateral retrograde femoral access. Specifically, an antegrade ipsilateral femoral access, which is well known for its increased support and torque control [22] was used overall in 19 (12.5%) limbs, without significant differences in the standard access site versus retrograde popliteal access (16 [12.6%] versus 3 [12.0%], respectively, $P = 1.0$).

The popliteal artery was successfully punctured by fluoroscopy in all cases, enabling in all limbs the deployment of a short 4 Fr sheath. Then, standard guidewires of increasing aggressiveness, stiffness and hydrophilicity were used, supported by catheters or balloons. In most cases of combined femoral and popliteal access, long femoral sheaths were used with a contralateral retrograde femoral access.

Procedural success was achieved in 92 out of 107 patients (86.0%) treated with a standard approach and 22 out of 23 patients (95.7%) treated with retrograde popliteal access (total 114 out of 130 patients [87.7%]) and 112 out of 127 limbs (88.2%), and 24 out of 25 limbs (96.0%), respectively (total 136 out of 152 limbs [89.5%]). No significant increase in early or long-term adverse events was associated with retrograde popliteal access (Table III). Notably, antegrade femoral access was not associated with significant differences in success rates (17 [89.5%] versus 117 [89.3%], $P = 1.0$).

DISCUSSION

This study has three major implications: (a) standard access sites for challenging occlusions of the SFA still face a significant risk of failure; (b) using a retrograde popliteal access as bail-out strategy significantly increases success rates; (c) these benefits are not counterbalanced by an unduly increase in adverse events, including local access site bleeding.

Thanks to major advancements in techniques and devices, endovascular therapy has gained momentum and now challenges the traditional leading role of bypass surgery in several patient subsets. However, selected patients with extremely complex lesions still fare better with bypass surgery, which has remarkably high long-term patency rates, especially when autologous veins are employed. Nonetheless, several patients are not candidate to bypass surgery because of comorbidities, or prefer endovascular therapy despite being thoroughly informed of the differences in risks and benefits in comparison to surgery.

To further improve results of endovascular therapy for lower limb atherosclerosis, improvements must occur into two different realms: early success and long-term patency. Although only medical therapy and selected devices (e.g., stents) [23] are likely capable of improving long-term patency rates, novel techniques and dedicated devices are required to improve procedural success rates. Recanalization attempts of SFA occlusions are at high risk of failure when there are difficulties in re-entering the true lumen after a long subintimal track. In this case, dedicated re-entry devices have been proposed, such as the Outback (Cordis), the Pioneer (Medtronic, Santa Rosa, CA), and the

SPOT System (Boston Scientific, Natick, MA) [4,24,25]. However, their costs and requirements for learning curve have limited their use so far.

The alternative to dedicated devices is a unique technique based on concomitant femoral and popliteal access, which exploits the common presence of a tapered distal stump of the SFA occlusion. This approach, based on the use of 3 to 6 Fr sheaths (but which can also be performed sheathless with a 0.018" guidewire and compatible balloon) is applicable in all but those patients with significant atherosclerotic involvement of the popliteal artery.

Prior studies have already established the important impact on success rates of concomitant femoral and popliteal accesses, after the first pioneering description by Tonnesen et al. in 1988 [5,6,10–18,26]. In particular, Henry et al. reported on 30 patients in 1993 in which popliteal access was associated with a success rate of 80% [11]. Saha et al. described in 2001 the use of popliteal access in 38 limbs with ilio-femoral lesions (including both stenoses and occlusions), with final success in 97% [26], whereas in the same year Yilmaz et al. provided data on 39 cases of SFA occlusion, with successful recanalization in 82%.[12] In another large subset, Noory et al. attempted retrograde popliteal access in 56 patients, achieving a successful recanalization in 98%.[17] However, none of these works explicitly compared safety and efficacy of a combined femoral and popliteal access to a femoral only access.

Indeed, our work clearly builds upon previous works on this topic, confirming that popliteal access significantly increases success rates, achieving on average a successful revascularization in 85–95% of patients. In addition, our study provides further support to the safety of the popliteal access, especially when puncture is meticulously performed, in the absence of diseased popliteal segments, and, in our opinion, without relying on access closure devices [16,17]. From a technical perspective, popliteal access can be obtained with fluoroscopic guidance or ultrasound guidance,[14] and with the patient in a lateral or prone position. In addition, a sheathless approach (with 0.018" guidewires and suitable balloons) can be chosen or, more commonly, a 3–6 Fr sheath. We recommend however, whenever possible, to choose a prone position, puncture the artery under fluoroscopic guidance with road mapping, and deploy a 4 Fr sheath to maximize support and minimize local bleeding. Such a sheath enables the use of any guidewire, several balloons, and can be easily exchanged for larger ones if stenting is attempted also retrogradely. Conversely, hemostasis with a 4 Fr sheath is easily and quickly achieved manually, thus reducing the risk of local vessel complications.

Our work has several limitations, including the retrospective design, the obvious selection bias which reflects the complex operators' judgments and decisions before and after retrograde popliteal access. Indeed, the decision of using such approach was altogether subjective, and several baseline patient and lesion characteristics, such as prevalence of prior target intervention, may bias the results again standard femoral access. Accordingly and also given the differences in size of the analyzed groups, statistical comparisons should be viewed mainly as hypothesis generating. Finally, occlusion stump shape, use of intraluminal versus subintimal angioplasty, procedural time, and fluoroscopy time, despite being important to compare standard and popliteal approaches, were not collected in the study case report form and thus their analysis is beyond the scope of our work.

CONCLUSIONS

Whenever standard accesses (i.e., femoral or brachial) do not enable successful recanalization of SFA occlusions, a retrograde popliteal access can be safely and effectively envisioned as bail-out strategy.

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